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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,266	06/09/2006	Michael Chorny	CHOP-101US	1341

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,266	CHORNY ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *18 and 37-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060609*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-36, drawn to a particle comprising a complex formed by a bioactive agent and a complexing agent, provided that the bioactive agent is other than a polynucleotide and an oligonucleotide in the reply filed on August 10, 2007 is acknowledged. Acknowledgment is made of the species of a bioactive agent identified as PDGF (platelet-derived growth factor), a complexing agent as dextran, and a biodegradable polymer matrix for initial examination. Applicants state that claims 1-36 read on the elected species. Claim 18 further requires an agent, which was not elected and therefore does not read on the elected species. The election was made without traverse.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 18, and 37-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 10, 2007.

3. Claims 1-17, and 19-36 drawn to a species comprising PDGF as the bioactive agent, dextran as the complexing agent, and a biodegradable matrix are currently under examination.

Priority

4. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is December 9, 2003.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on June 9, 2006 is being considered by the examiner.

Specification

6. The disclosure is objected to because of the following informalities:

7. In the brief description of the drawing section, Figure 4 is described as having a white part and a shaded part, although the figure does not disclose a shaded part. Suggest correcting description to correlate with Figure 4.

8. On page 14, line 27, the word, "dextrane" appears to be intended to be ---dèxtran---. Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 12, 13, and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 is rejected for failing to describe the receptor fragments for FGF, PDGF, VEGF, and CAR. The claim does not recite a functional limitation for the fragments, and it is

reasonably interpreted that any fragment from the receptors would not function in the particle as a bioactive agent. Claims 13, and 32 are rejected for failing to describe the structural modifications and derivatives for the complexing agents and anionic agents in the Markush members recited. The moieties are defined only by their functional characteristics (e.g. complexing agent).

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one

skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high adequate written description would require fewer species to be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? The claims are drawn to a particle comprising a complex formed by a bioactive agent and a complexing agent, wherein the complexing agent is a member selected from the group consisting of polysaccharides, glycosaminoglycans, complex carbohydrates, polyacids, modifications and derivatives thereof.

Second, how does the scope of the claims compare to the scope of the disclosure? The disclosure contains the same language found in claims and also discloses the specific anionic complexing agent as dextran sulfate. Thus, the specification is more detailed than claims drawn to any modifications and derivatives of any anionic complexing agent.

Third, the factors need to be considered.

(1) What was actually reduced to practice?

Clearly, the method of manufacturing a PDGF-BB particle with dextran sulfate as the complexing agent was actually reduced to practice.

(2) Is there disclosure of drawings or structural chemical formulas?

No general structure is provided for each anionic complexing agent or any such modifications and derivatives thereof.

(3) Are there sufficient relevant identifying characteristics disclosed?

There are insufficient identifying structural characteristics disclosed for the genus of anionic complexing agents, particularly for any modifications and derivatives thereof.

(4) Is there at least one method of making the claimed invention disclosed?

The PDGF-BB particle using the dextran sulfate complexing agent was disclosed.

(5) What is the level of skill in the art and what knowledge is present in the art?

The level of skill in the art of manufacturing bioactive agent containing particles is high, about that of a PhD scientist with several years' experience.

(6) What is the level of predictability of the art?

The level of predictability in this art is very low since, until the particle containing the bioactive agent is examined, there is no information upon which to base a prediction of what molecule might be suitable as anionic complexing agents.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of species which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention for modified and derivatives of any complexing agents.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-17, and 19-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Schacht et al. (U.S. Patent 6,458,386 B1).

Schacht et al. disclose a composition containing a biopolymer matrix comprising constituents selected from the following: a. a methacrylamide modified gelatin and a polysaccharide, wherein the gelatin is modified with methacrylamide side groups which are capable of being radically cross-linked; or b. a gelatin and a vinyl-substituted polysaccharide, wherein the polysaccharide is modified with vinyl side groups which are capable of being radically cross-linked; or, c. a methacrylamide modified gelatin and a vinyl-substituted polysaccharide wherein the gelatin has been modified with methacrylamide side groups which are capable of being radically cross-linked and the polysaccharide has been modified with vinyl side groups which are capable of being radically cross-linked; wherein the respective matrix constituents are physically entrapped in the matrix, after radically induced cross-linking polymerization or radically induced cross-linking copolymerization, so that they form a semi-interpenetrating network. The composition, wherein the biopolymer matrix further comprises one or a mixture of two or more of the following compounds: a polysulfated oligo- or polysaccharide or fragments thereof; a biocompatible polyanion which has the capacity to bind heparin-binding growth factors; a proteoglycan containing glycosaminoglycan chains capable of

binding to heparin-binding growth factors; a functional analogue of heparin which binds or stabilizes heparin-binding growth factors; a monoclonal or polyclonal antibody or a microprotein wherein said antibody or microprotein has a high and selective affinity for molecular factors that can modulate the wound healing process, and wherein said microprotein can be obtained by phage display; a therapeutically effective amount of a drug; compounds having substantial affinity for the incorporated drug, so as to slow down the release of the drug from the matrix and/or stabilizing the drug. Schacht et al. disclose a controlled or slow release device comprising microparticles of a composition loaded with a drug, which can be injected intravenously, subcutaneously, or intramuscularly. The composition, wherein the polysulfated oligo- or polysaccharide is selected from one or more of the following: heparin, heparin sulfate, chondroitin sulfate, dermatan sulfate, and dextran sulfate. The composition, wherein the drug is selected from the group consisting of an EGF, a FGF, a TGF-.beta., an IGF, a PDGF, and keratinocyte cell lysate (see claims 1, 2, 12, and 19).

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 13, 2007

AD
/Anand Desai/
Patent Examiner
Art Unit 1656